K110334
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APR 12 2011

Waldo Health
Waldo Health Patient Monitor

510(k) Summary

SUBMITTED BY	Waldo Health 4505 Spicewood Springs Road, Suite 333 Austin, Texas 78759 USA
ESTABLISHMENT REGISTRATION NUMBER	Pending
OWNER/OPERATOR NUMBER	10034522
CONTACT PERSON	Primary Alan R. Weiss Co-Founder/CTO Waldo Health Phone: 512-219-0302 Fax: 512-219-0402 Alternate Samuel B. Fuller Co-Founder/CEO Waldo Health Phone: 512-219-0302 Fax: 512-219-0402
SUBMISSION PREPARED BY	Lisa Peterson QA Consulting, Inc. Phone: 512-507-0746
DATE PREPARED	December 14, 2010
CLASSIFICATION NAME	Transmitters and Receivers, Physiological Signal, Radiofrequency
DEVICE CLASS	Class II
REGULATION NUMBER	870.2910 (Product Code DRG)
COMMON NAME	Remote Patient Monitoring System
PROPRIETARY NAME	Waldo Patient Monitor
IDENTIFICATION OF PREDICATE DEVICE(S)	Predicate devices include: - Intel Health Guide PHS6000 (K080798) - MedApps 2.0 (K083862)

DEVICE DESCRIPTION

The Waldo Patient Monitor is a remote patient monitoring device available via prescription.

The Waldo Patient Monitor connects to commercially available wireless and tethered glucose meters, weight scales, blood pressure monitors and pulse oximeters, stores and displays the information on the LCD screen and transmits the information to the Waldo Health secure server. Healthcare professionals can review the transmitted information utilizing the Waldo Health Clinician Access System.

The Waldo Health System consists of:

1. Waldo Health System Hardware:

   The physical component of Waldo Health System is the Waldo Patient Monitor, which is an electronic device contained in an acrylonitrile butadiene styrene (ABS) thermoplastic enclosure with a touch screen, built-in video camera, microphone, speaker, and a reminder light ("light bar") mounted on top of the case. The Waldo Patient Monitor contains front and back panels that provide standard USB 2.0 connectors, Ethernet connector, power connector and power button, as well as volume controls.

2. Waldo Patient Monitor Software Application:

   The Waldo Patient Monitor executes the Waldo Patient Monitor Software Application, which connects to commercially available wireless and tethered glucose meters, weight scales, blood pressure monitors and pulse oximeters, stores and displays the information on the LCD screen and transmits the information to the Waldo Health secure server.

3. Waldo Health Clinician Access System (CAS) Software Application:

   The Waldo Health Clinician Access System (CAS), which is associated with and manages multiple Waldo Patient Monitor devices, is designed to allow doctors and nurses to create and access electronic health records as well as provide a user-friendly interface into a patient's health condition.

The Waldo Health System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. The system is contraindicated for patients requiring direct medical supervision or emergency intervention. The system is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

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INDICATIONS FOR USE

The Waldo Patient Monitor is a remote patient monitoring device. The Waldo Patient Monitor connects to commercially available wireless and tethered glucose meters, weight scales, blood pressure monitors and pulse oximeters. The Waldo Patient Monitor stores and displays the information on the LCD screen and transmits the information to the Waldo Health secure host server using connectivity including, but not limited to, FCC approved Wi-Fi, or Ethernet.

Healthcare professionals can review the transmitted information utilizing the Waldo Health Clinician Access System and set thresholds to trigger alerts based on specific thresholds being exceeded.

The Waldo Health System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The system is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

A list of devices that are compatible with the Waldo Health System will be available in the user's manual and the Waldo Health website.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Waldo Health System is substantially equivalent to the predicate devices in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be interfaced to the patient device, implementation method of collecting data from sensors, sensor software, connectivity, communication protocol, power source and display method.

DISCUSSION OF NON-CLINICAL TESTING

Non-clinical testing consisted of bench testing using Waldo Health procedures and specifications, usability testing under duplicated operating conditions and performance standards testing in accordance with IEC 60601-1 and IEC 60601-1-2. The results demonstrated that the Waldo Health System met performance and design specification requirements.

CONCLUSIONS

The subject and predicate device(s) are substantially equivalent in terms of intended use and technological characteristics. Non-clinical mechanical test results demonstrate that the Waldo Health System performance is satisfactory and suitable for its intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Waldo Health
c/o Mr. Alan R. Weiss
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APR 12 2011

Re: K110334
Waldo Patient Monitor
Regulatory Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitters and Receivers
Regulatory Class: II (two)
Product Code: DRG
Dated: April 5, 2011
Received: April 6, 2011

Dear Mr. Weiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110334

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: **Waldo Patient Monitor**

Indications for Use:

The Waldo Patient Monitor is a remote patient monitor device available by prescription. The Waldo Patient Monitor is designed to be used in the home of a patient undergoing remote monitoring for maintenance of chronic disease. The Waldo Patient Monitor provides guidance in operating medical sensor devices, reminders for medication compliance and connectivity to healthcare professionals through text messaging and real-time video conferencing technology.

The Waldo Patient Monitor connects to commercially available wireless and tethered glucose meters, weight scales, blood pressure monitors and pulse oximeters. The Waldo Patient Monitor stores and displays the information on the LCD screen and transmits the information to the Waldo Health secure host server using connectivity including, but not limited to, FCC approved Wi-Fi, Cellular Wireless Internet or Ethernet.

Healthcare professionals can review the transmitted information utilizing the Waldo Health Clinician Access System and set thresholds to trigger alerts based on specific thresholds being exceeded.

The Waldo Health System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The system is intended for patients who are willing and capable of managing its use. Judgment and experience by a caregiver or by a family member are required to check and interpret the information delivered.

A list of devices that are compatible with the Waldo Patient Monitor will be available in the user's manual and the Waldo Health website.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110334

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